REMARKS

The only ground of rejection of the pending claims is on the basis that the specification does not enable the scope of the claims. This ground of the rejection comprises two issues.

The first issue is whether the specification enables *prevention* of diseases or conditions which are otherwise treatable by retinoic acid and/or retinoids. In view of the Examiner's argument that the burden of proving *prevention* is much greater than the burden of proving treatment, the applicant, acting through the undersigned attorney, has amended all claims, as applicable, to delete the term "prevent", "preventing" or "prevention".

The second issue is whether the specification enables treatment of a disease or condition of the type treatable by retinoid acid and/or by retinoids by co-administering with a "retinoid" (such as Vitamin A, retinoic acid or other retinoids) compounds of *defined structure* which are inhibitors of the enzyme CP450RAI. The enzyme CP450RAI is known to act to catabolize (destroy "retinoids"). The applicant strongly argues that on this issue the Examiner's negative view is in error. The reasons are as follows.

There is no dispute that the specification enables a showing that the compounds of defined structure in the claims are inhibitors of the enzyme CP450RAI.

The specification teaches and the attached scientific publications by *V.C.O Njar, in Mini Reviews in Medicinal Chemistry,* ***2002****, 2, 261 – 269,* Cytochrome P450 Retinoic Acid 4-Hydroxylase Inhibitors; Potential Agents for Cancer Therapy (**EXHIBIT 1**), by *W.H. Miller in CANCER October 15, 1998 /* ***Volume 83*** */ Number 8, 1471 – 1482,* The Emerging Role of Retinoids and Retinoic Acid Metabolism Blocking Agents in the Treatment

of Cancer (**EXHIBIT 2**), and the attached Expert Declaration by Jayasree Vasudevan Ph. D. (**EXHIBIT 3**) clearly show that a person of ordinary skill in the art will readily understand, in light of the present specification, that the therein claimed compounds can be utilized in co-administration with "retinoids" (including vitamin A and retinoic acid) exactly for the type of diseases which are treatable by such "retinoids". The foregoing clearly follows from knowing or recognizing the diseases treatable by "retinoids" and from the present disclosure that shows the compounds of the claims to be inhibitors of the catabolic breakdown of retinoids.

It is applicant's position that providing data to disclose specific diseases which *per se* are treatable by retinoids is not necessary to provide enablement for the co-administration of the present compounds with the retinoids utilized to treat such diseases. The present specification and claims describes and define dosages and routes of administration, as applicable pertaining to the claimed methods.

In further support of applicant's position on this issue applicant urges that the standard of patentability is not on the same level as the standard under which regulatory agencies, such as the Food and Drug Administration (FDA) may allow the actual use of a pharmaceutical agent in the country. Inasmuch as the diseases are known, (and/or are constantly being further identified) which can be treated by "retinoids" then the present disclosure showing that the compounds of the claims inhibit the breakdown of such "retinoids" provides sufficient enablement for the instant claims. Thus, applicant urges that a showing of actual data regarding specific diseases is not required for enablement.

With respect to the Examiner's Statement on the first page of "Detailed Action" in the last Office Action regarding the Supplemental

Information Disclosure Statement, applicant responds as follows. The Supplemental IDS of May 8, 2006 did NOT purport to state that the *Alegretto et al. J. Biol. Chem. 268(35): 26625 – 26633 (1993)* and *Cheng, et al., Biochemical Pharmacology, 22(23): 3099-3108 (1973)* were newly submitted references. On the contrary the Supplemental IDS stated that these references were previously submitted in applicant's original IDS but were not fully or correctly identified. This information is correct. In fact, the "signed off" form of the IDS (signed by the Examiner on October 21, 2005) indicates that these references had indeed been considered, although their title or place of publication may not have been fully stated in applicant's original IDS.

In light of the foregoing, all outstanding claims of the present application are in *prima facie* allowable condition, and their early allowance is respectfully solicited.

In the event the Examiner is of the opinion that a telephone conference with the undersigned attorney would materially facilitate the final disposition of this case, she is respectfully requested to telephone the undersigned attorney at the below listed telephone number.

Respectfully submitted

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